DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

9/6841

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kye Shin
Chief Executive Officer
Daebok Restaurant
29-22 Union Street
Flushing, New York 11354

August 17, 2001

REF: NYK-2001-95

Dear Mr. Shin:

We inspected your firm located at the above address on June 6, 2001 as a follow-up to a previous inspection conducted on February 16, 2001. These inspections found that you had and continue to have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulation, Part 123(21CFR 123). These deviations were previously brought to your attention in our letter of March 8, 2001 and June 4, 2001, cause your fillet shad and oysters to be in violation of section 402 (a) (4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links on FDA's home page at (www.fda.gov).

The deviations were as follows:

(A) Your firm lacked product specifications for Fillet Shad and Oysters that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. Because it may be injurious to health or have been processed under insanitary conditions.

(B) Your firm lacks any of the affirmative steps ensuring that the Fillet Shad and Oysters are being processed in accordance with the Seafood HACCP regulations as per 21 CFR 123.12 (2)(ii)(A-F).

(B) Your firm also fails to have a written guarantee from the foreign processor that The imported fish and fishery products have been processed in accordance with the Seafood HACCP regulations as per 21 CFR (2)(ii)(D).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/ enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Mildred B. Harris Compliance Officer, 158-15 Liberty Avenue, Jamaica, N.Y. 11433. If you have any questions regarding any issue in this letter, please contact Ms Harris at 718/349-7000 ext.5479.

Sincerely yours,

Robert L. Hart
Acting District Director
New York District